K003936

TOMTEC IMAGING SYSTEMS

FEB 1 4 2001

November 15th 2000

510(k) Summary
Panoramic View

Name and Address

TomTec Imaging Systems GmbH
Edisonstrasse 6
D-85716 Unterschleissheim

Contact Person

Florian Eisenberger
Director, Regulatory Affairs & Quality Assurance
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Common, Classification & Proprietary Names

Common Name:	Digital Ultrasound Image Analysis System
Classification Name:	Ultrasonic Pulsed Echo Imaging System
Proprietary Name:	Panoramic-View
	Panoramic-Scan
	WIDAS
	Wide Area Scanning

Predicate Device

Acuson FreeStyle K991805

Device Description

The Panoramic View Software allows visualization of anatomic structures over a wider filed of view that surrounds a particular region of interest. The feature operates in B-mode and Color Doppler modes with standard ultrasound systems and their transducers for all indications for use except cardiac, ophthalmic, and transcranial uses.

The Panoramic View Software collects a series of Ultrasound-Images and stiches the images together to generate a large composite image of the anatomic structure. The composite image is displayed and can be stored for later review.

The frames can be captured over maximum 70 cm linear distance.

The Panoramic View is a software module which requires high performance computer systems based on Microsoft Windows NT™ 4.0 operating system standards. The Software runs on ultrasound integrated computers or TomTec

proprietary acquisition systems as used for Echo-Scan and Easy-Scan Acquisition systems.

There is also a measurement capability (not in first release) in the PC software that can be used on the B mode extended images to perform distance and length measurements. The Color Doppler extended images are used to detect the presence or absence of blood flow and are not for quantification.

Intended Use

Panoramic View provides images of anatomy in an extended field of view as wide area composite image display (panoramic view)
Panoramic View is intended to acquire, store, retrieve and analyze digital ultrasound images and Color Doppler images for computerized panoramic image processing.
Panoramic View can import certain digital 2D image file formats for panoramic reconstructions. It is intended as a general purpose image acquisition and image processing tool for radiology, gastro-enterology, urology, surgery, obstetrics and gynecology.
The indications for use include fetal, small organ, peripheral vessel, abdominal, gynecologic, transrectal, intraoperative, and musculoskeletal uses.

Technological Characteristics Comparison

The Panoramic View is comparable to the Acuson FreeStyle Imaging Option as it performs the same fundamental characteristics. The TomTec Panoramic View has been developed to allow panoramic scanning on standard ultrasound systems .

Test Discussion

Testing was performed according to internal company procedures. Software testing and validation were done at the module and system level according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release.

Test Conclusions

Test results support the conclusion that actual device performance satisfies the design intent. Actual device performance as tested internally conforms to the system performance specifications.

December 13th , 2000 Florian Eisenberger

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2001

Florian Eisenberger
Regulatory Affairs Manager
TOMTEC Imaging Systems, GMBH
Edisonstrasse 6
D-85716 UNTERSCHLEISSHEIM
BAVARIA GERMANY

Re: K003936
Panoramic View Software
Dated: December 14, 2000
Received: December 20, 2000
Regulatory Class: II
21 CFR §892.1560/Procode: 90 IYO

Dear Ms. Eisenberger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known):_____

Device Name:_ TOMTEC Panoramic View

Indications For Use

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(PLEASE DO NOT WRITE BELOW LINE LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003936